

REMARKS

Claims 2-14, 16 and 17 are pending in the present application and are subject to a restriction requirement. Applicants request reconsideration of the aforementioned Restriction Requirement in view of the remarks set forth below.

I. Election/Restriction

The Action alleges that restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I: Claims 2-14 and 16 -17 drawn to a method for treating pain with the compound of the formula (I) when E is N, classified in class 514, subclass 394;

Group II: Claims 2 - 7, 12 - 14 and 16 - 17, drawn to a method for treating pain with the compound of the formula (I) when E is CH, classified in class 514, subclass 415;

Group III: Claims 2 - 14 and 16-17 drawn to methods of using compounds of formula (I) when E is radical, classified in class 514, subclass 419.

In addition to the above, the Action further requests election of a single product/species and the claims readable on the elected product/species.

In requiring the above restriction/election, the Action states that: "there would be a serious burden on the examiner if restriction is not required because the inventions have acquired separate status in the art in view of their different classification." (Action at 2). In addition, the Action alleges that Applicants must also elect a single species from the compound(s) and disease(s) along with a list of claims readable thereon. The Action cites 35 U.S.C. § 121 as providing a basis for sustaining the aforementioned requirement

III. Applicant's Response

(a) Applicants Election

Pursuant to MPEP § 818.03(c), Applicants traverse the restriction requirement because the Action has failed to procedurally and substantively meet the legal requirements for the Requirement. Applicants elect, with traverse, Group II wherein E is CH; along with the compound, N-[(S)-2-Diphenylamino-1-(5-oxo-4,5-dihydro-[1,3,4]oxadiazol-2-yl)ethyl]-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide.

(b) Response

To the extent the Action requires Applicants to elect a single Markush species within independent method claim 2, at the exclusion other recited species within the claim, Applicants submit that such a requirement cannot be sustained as a matter of law, absent a showing that the claimed species are either patentably distinct or exceed a reasonable number of species. Although 35 U.S.C. § 121 authorizes the Commissioner (Director) to substantively restrict an application claiming two or more inventions to a single invention, procedurally, § 121 does not alleviate the Examiner of demonstrating the aforementioned prerequisites. The Action must either provide reasoning to support the requirement for restriction - more than mere conclusions that the alleged inventions are "independent or distinct" or demonstrate that the species exceed a reasonable number causing a burden for Examination. Moreover, an Applicant may not be required, "under the guise of § 121, to divide up the embodiments of a single Markush claim." In re Weber, 580 F. 2d 445 (C.C.P.A. 1978). The elected species and Group must be examined, and if allowable, the non-elected species must also be examined. (MPEP 803.02).

The Action has improperly required Applicants to parse out, at least, claim 2 by indicating the following: "Upon allowance of a generic claim, application will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitation of allowable generic claim as provided ..." (Action page 3). Applicants contend that the aforementioned generic claim (Claim 2), beginning with the elected Markush species

within the claim must be examined, and if allowable, the additional non-elected species must be examined.

It is improper for the Action to require parsing of a single claim. In re Weber is instructive as authoritave case law. Specifically, the CCPA has stated:

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of § 112.

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. ... If, however, a single claim is divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In re Weber, Soder, and Boksay, 198 USPQ 328, 331 (CCPA 1978).

As noted abouve, Applicants have elected, with traverse, Group II wherein E is CH, along with the compound, N-[*(S*)-2-Diphenylamino-1-(5-oxo-4,5-dihydro-[1,3,4]oxadiazol-2-yl)ethyl]-2-(2-methylaminopyrimidin-4-yl)-1H-indole-5-carboxamide, as a species for initial examination. If allowable, the non-elected species from the same claim should then be examined. By contrast, the Action's requirement that Applicants elect the species of Group I, at the exclusion of the non-elected species (Group II and III) from consideration, before the elected species is examined against any prior art is improper. (See, MPEP 803.02).

Significantly, such a requirement contradicts the above-described principles of Restriction. C In re Weber is an example of case law which supports an Applicant's statutory right to claim his invention with the limitations he regards as necessary to circumscribe that invention; with the proviso that the application complies with the requirements of § 112. Thus, requiring an Applicant to limit her claimed invention to one species or embodiment, curtails Applicants aforementioned right. At the very least, the Action must first cite prior art that compromises the patentability of the elected species. Accordingly, in view the aforementioned procedural and substantive deficiencies, Applicants submit that Action's requirement to parse out the Markush claim between the elected and non-elected species within the claim cannot be sustained and must be withdrawn.

Applicants further point out that the Action's requirement to withdraw non-elected subject matter within the claim is also improper for another for reasons related to Unity of Invention. Specifically, Unity of Invention exists between the Markush group of species where the species share: (1) a common utility; and (2) a substantial structural feature disclosed as being essential to that utility, unity of invention is recognized.

In the present case, Applicants' elected species share a common utility, namely, their ability as substituents on the structure of formula 1 to modulate pain through the inhibition of IkB-kinase. Second, the elected species also share a common substantial structural feature, as located on the indole ring. So, in view of the above, Applicants submit that the Action's restriction requirement to parse out the Markush species cannot be sustained and must be withdrawn.

IV. Conclusion

In summary, Applicants maintain that procedurally, the Action's requirement to withdraw non-elected subject matter within the claim is improper because it requires Applicants to parse out the non-elected species, before citing prior art against the elected species, and (2) substantively, a restriction requirement under § 121 cannot be applied to a single claim under the holding of In re Weber et al., especially where the elected species share a common utility an

Early indication of allowable subject matter is earnestly solicited. Should there be any issues to that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited to call the undersigned attorney.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. **18-1982** in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

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